

**REMARKS**

Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, and 61-72 are pending and under consideration. In light of the following remarks, Applicants respectfully request reconsideration of this application and allowance of the claims to issue.

Filed herewith are a Declaration under 37 C.F.R. § 1.131 of Bruce L. Gibbins, Ph.D. and a Petition for a Three-Month Extension of Time.

**35 U.S.C. § 103**

Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-72 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Ladin (U.S. Patent No. 5,792,090, of record) in view of Gibbins (U.S. Patent No. 5,928,174, currently listed on PTO 892) and Murdock (U.S. Publication No. 2002/0042587, of record).

The Office Action states that present Claims 1, 38, and 39 “recite a product that comprises a matrix of closed cell foam of cross-linked polyacrylamide polymer containing oxygen produced by reaction of catalyst and reactant. The limitation of oxygen delivery is directed to intended use that impart patentability to composition claims. The limitation when oxygen is produced in the crosslinked polyacrylamide network is directed to process of making the product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 777 F.2d 695,698, 227 USPQ 964, 966 (Fed. Cir. 1985).”

The Office Action states that “Ladin teaches wound dressing that supply oxygen to the wound for optimal healing and minimization of infection because the wound causes diffusion limited access and limits the oxygen supply to the wound (abstract; col.2, lines 28-31). The dressing comprises polymeric foam comprising elements that react to generate oxygen that are hydrogen peroxide and catalyst such as magnesium dioxide or enzymes (col.6, lines 6-26). The catalyst is contained in the foam which absorbs hydrogen peroxide into the foam to produce oxygen (col.7, lines 48-55). The foam comprises guar gum or polyacrylamide, and further comprises collagen, i.e. non-gellable foam (col.4, lines 39-42; col.12, line 7). Although Ladin

teaches polyacrylamide foam, however, the reference does not explicitly teach crosslinked polyacrylamide or closed cell foam in particular.”

The Office Action states that “Gibbins teaches wound dressing comprising cross-linked polyacrylamide polymer matrix that is flexible and elastic, permeable to substances such as aqueous fluids and dissolved gaseous agents including oxygen. (See col.4, lines 62-67; col.5, lines 12-17).”

The Office Action states that “Murdock teaches polymeric cross-linked foam reservoir comprising cellulose derivatives and active agent including anti-infective agents and growth factors (abstract; paragraphs 0035, 0049, 0050). The foam reservoir is closed cell foam wherein the closed cells can be produced chemically and contains gasses including oxygen (paragraph 0036). The closed cell foam provides thin matrix with high surface area with respect to the matrix (paragraphs 0011, 0016).”

The Office Action goes on to state that “... at the time of the invention it was known to treat wound using polyacrylamide foam matrix containing oxygen produced by chemical reaction between peroxide and catalyst as taught by Ladin, and replace polyacrylamide by crosslinked polyacrylamide taught by Gibbins. One would have been motivated to do so because Gibbins teaches that cross-linked polyacrylamide polymer matrix that is flexible and elastic, permeable to substances such as aqueous fluids and dissolved gaseous agents including oxygen. One would reasonably expected formulating elastic flexible crosslinked polyacrylamide foam matrix containing oxygen that is produced chemically by the reaction of peroxide and catalyst wherein the foam is optimal for wound healing and can accommodate the oxygen released by the reaction of peroxide and catalyst.”

The Office Action states that “... it would have been obvious to one having ordinary skill in the art at the time of the invention to use the closed cell foam taught by Murdock in the foam matrix taught by the combination of Ladin and Gibbins because Murdock teaches that closed cell crosslinked polymer foam matrix is thin and has high surface area with respect to the matrix and oxygen can be delivered chemically in foam. One would reasonably expect formulating elastic flexible crosslinked polyacrylamide closed cell foam matrix containing oxygen that is produced by the reaction of peroxide and catalyst wherein the matrix is thin, yet can accommodate oxygen and therapeutic agents.”

The Office Action goes on to state that the “ultimate legal conclusion is that the subject matter defined by the claims would have been *prima facie* obvious within the meaning of 35 U.S.C. 103 (a) because the invention as a whole is taught by the combined teaching of the cited references.”

Courts have generally recognized that a showing of a *prima facie* case of obviousness necessitates three requirements: (i) some suggestion or motivation, either in the references themselves or in the knowledge of a person of ordinary skill in art, to modify the reference or combine the references’ teachings; (ii) a reasonable expectation of success; and (iii) the prior art references must teach or suggest all of the claim limitations. See e.g., *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999); *In re Rouffet*, 149 F.3d 1350, 1355 (Fed. Cir. 1998); *Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

“Before answering Graham’s ‘content’ inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102.” *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1987). Subject matter that is prior art under 35 U.S.C. 102 can be used to support a rejection under section 103. *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. Pat. App. & Inter. 1981) (“it appears to us that the commentator [of 35 U.S.C.A.] and the [congressional] committee viewed section 103 as including all of the various bars to a patent as set forth in section 102.”).

“A 35 U.S.C. 103 rejection is based on 35 U.S.C. 102(a), 102(b), 102(e), etc. depending on the type of prior art reference used and its publication or issue date. For instance, an obviousness rejection over a U.S. patent which was issued more than 1 year before the filing date of the application is said to be a statutory bar just as if it anticipated the claims under 35 U.S.C. 102(b). Analogously, an obviousness rejection based on a publication which would be applied under 102(a) if it anticipated the claims can be overcome by swearing behind the publication date of the reference by filing an affidavit or declaration under 37 CFR 1.131.” See M.P.E.P. § 2141.01I.

The Office Action relies on three references (Ladin, Gibbins and Murdock) to allege that the claimed invention is obvious. However, one of the three references (Gibbins, the ‘174 patent) does not qualify as prior art. Gibbins (the ‘174 patent) was filed on November 14, 1997 and issued on July 27, 1999 (the publication date and issue date). The instant application was

filed on December 29, 2000 and claims the benefit of U.S. Provisional Patent Application No. 60/174,024, which was filed on December 30, 1999 (the effective date of the instant application).

The '174 patent cannot be asserted as prior art to reject the claimed invention under 35 U.S.C. § 103(a) because it does not qualify as prior art for the claimed invention under 35 U.S.C. § 102(a), (b), or (e).

With regard to 35 U.S.C. § 102(a):

(i) Bruce Gibbins is a co-inventor of the instant application and the sole inventor of the '174 patent. Thus, the '174 patent and the instant application have different inventive entities;

(ii) The '174 patent was issued (published) less than one year before the effective date of the instant application; however,

(iii) Bruce Gibbins submits herewith a Declaration under 37 C.F.R. § 1.131 in which he swears behind the '174 patent. Thus, the '174 patent does not qualify as prior art for the instant application.

With regard to 35 U.S.C. § 102(b):

(i) The '174 patent was issued (published) less than one year before the effective date of the instant application;

(ii) Therefore, the '174 patent does not qualify as prior art for the instant application.

With regard to 35 U.S.C. § 102(e):

Applicants traverse this rejection because there is no legal basis for this rejection. Specifically, the rejection of Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, 61-72 under 35 U.S.C. § 103(a) is improper because under 35 U.S.C. § 103(c), "subject matter which was prior art under former 35 U.S.C. 103 via 35 U.S.C. 102(e) was disqualified as prior art against the claimed invention if that subject matter and the claimed invention 'were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.'" See M.P.E.P. § 2146.

"In order to be disqualified as prior art under 35 U.S.C. 103(c), the subject matter which would otherwise be prior art to the claimed invention and the claimed invention must be commonly owned, or subject to an obligation of assignment to a same person, at the time the claimed invention was made or be subject to a joint research agreement at the time the invention

was made.” See M.P.E.P. § 706.02(1)(2). “The term “commonly owned” is intended to mean that the subject matter which would otherwise be prior art to the claimed invention and the claimed invention are entirely or wholly owned by the same person(s) or organization(s)/business entity(ies) at the time the claimed invention was made.” See M.P.E.P. § 706.02(1)(2)I.

“Applications and references (whether patents, patent applications, patent application publications, etc.) will be considered by the examiner to be owned by, or subject to an obligation of assignment to the same person, at the time the invention was made, if the applicant(s) or an attorney or agent of record makes a statement to the effect that the application and the reference were, at the time the invention was made, owned by, or subject to an obligation of assignment to, the same person.” See M.P.E.P. § 706.02(1)(2)II.

#### **STATEMENT OF COMMON OWNERSHIP**

In accordance with M.P.E.P. § 706.02(1)(2)II, Applicants assert that the instant application (U.S. Application No. 09/752,939) and U.S. Patent No. 5,928,174 were, at the time the invention of U.S. Application No. 09/752,939 was made, were commonly owned by Acrymed, Inc.

Therefore, Gibbins (the ‘174 patent) is disqualified as prior art for the instant application and thus cannot be asserted against the instant application under 35 U.S.C. § 103(a).

Moreover, neither Ladin nor Murdock, alone or in combination, teaches the claimed invention. Ladin does not teach “[a]n oxygen-delivery wound treatment device, comprising, a biocompatible, single unit matrix for delivering oxygen, comprising a) a swellable, cross-linked polyacrylamide polymer network, and b) deliverable oxygen in elastic closed cells that are permeable to gas within the cross-linked polyacrylamide polymer network wherein after the polyacrylamide polymer network is cross-linked, the closed cells are formed by oxygen, produced by reacting a catalyst and a second reactant, and wherein with use of the matrix, oxygen is delivered from the closed cells.” In fact, Ladin teaches an open cell polyacrylamide foam and makes no mention of cross-linking polyacrylamide.

Murdock does not teach “[a]n oxygen-delivery wound treatment device, comprising, a biocompatible, single unit matrix for delivering oxygen, comprising a) a swellable, cross-linked polyacrylamide polymer network, and b) deliverable oxygen in elastic closed cells that are permeable to gas within the cross-linked polyacrylamide polymer network wherein after the polyacrylamide polymer network is cross-linked, the closed cells are formed by oxygen, produced by reacting a catalyst and a second reactant, and wherein with use of the matrix, oxygen is delivered from the closed cells.” Instead, Murdock teaches a cross-linked polymeric closed cell foam but does not mention polyacrylamide.

Ladin and Murdock teach away from each other because Ladin teaches an open cell foam, and Murdock teaches a closed cell foam. Thus, there would be no motivation for a person of skill to combine the two references to make the claimed invention with a reasonable expectation of success.

Further, modification of the open cell foam as taught by Ladin to create a closed cell foam as taught in the instant application would render Ladin unsatisfactory for its intended purpose. According to the U.S. Court of Appeals for the Federal Circuit, “[i]f [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed invention.” (*In re Gordon*, 733 F.2d 900, 221 U.S.P.Q. 125 (Fed. Cir. 1984); see MPEP 2143.01).

The Office Action has failed to make a *prima facie* case of obviousness because (i) there is no suggestion or motivation, either in the references themselves or in the knowledge of a person of ordinary skill in the art, to modify the references or combine the references’ teachings; (ii) there is no reasonable expectation of success; and (iii) the prior art references alone or in combination do not teach or suggest all of the claim limitations.

Therefore, independent amended Claims 1, 38, and 39 would not be rendered obvious by the disclosures and teachings of the cited art. Likewise, the claims that depend from independent Claims 1, 38, and 39 would not be rendered obvious. See *In re Fine*, 5 U.S.P.Q.2d 1569, 1600 (Fed. Cir. 1988) (“Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious.”). Thus, Applicants respectfully request that this rejection be withdrawn and that independent Claims 1, 38, and 39 and dependent Claims 2, 4, 6, 8, 21, 23-28, 31-35, 40-43, 45-59, and 61-72 be allowed.

Pursuant to the above amendments and remarks, reconsideration and allowance of the pending claims are believed to be warranted, and such action is respectfully requested. The Examiner is invited to directly contact the undersigned if such contact may enhance the efficient prosecution of this application to issuance.

The foregoing is a complete response to the Office Action dated February 15, 2011. Applicants respectfully submit that at least Claims 1, 2, 4, 6, 8, 21, 23-28, 31-35, 38-43, 45-59, and 61-72 are patentable. Early and favorable consideration is solicited.

Applicants file this response solely to facilitate prosecution. As such, Applicants reserve the right to pursue claims of broader or similar scope as originally filed in a continuation application or other application after allowance of the present application. Applicants do not concede that the current or past rejections are correct and reserve the right to challenge such rejections later in prosecution or on appeal. Accordingly, any amendment, argument, or claim cancellation is not to be construed as abandonment or disclaimer of subject matter. Because certain of the current amendments may include broadening amendments, Applicants respectfully request the Examiner to revisit any previously reviewed references cited in this Application to further ensure that the currently pending claims remain patentable over any previously reviewed references.

A credit card payment submitted via EFS Web in the amount of \$1,110.00 (representing the fee for a large entity under 37 C.F.R. § 1.17(a)(3), a Declaration under 37 C.F.R. § 1.131 of Bruce L. Gibbins, Ph.D. and a Petition for a Three-Month Extension of Time are enclosed. This amount is believed to be correct; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,

BALLARD SPAHR LLP

/Mary Anthony Merchant, Reg. No. 39,771/  
Mary Anthony Merchant  
Registration No. 39,771

Customer Number 23859  
(678) 420-9300 Phone  
(678) 420-9301 Fax